

In the Claims:

1. (currently amended) ~~Process~~ A process for the ~~production of~~ producing a film-shaped preparation for administration of substances to the human or animal body, said preparation being disintegratable in aqueous media and containing at least one water-soluble polymer and at least one or more components gas-forming component which ~~produce~~ produces a gas upon action of moisture, ~~[[or]]~~ being in the presence of an aqueous medium or ~~in the case of~~ by a temperature change ~~in temperature~~, ~~by means of coating a coating compound or two coating compounds on a support~~, comprising the steps of:

[[-]] preparing a coating compound which contains the components of the preparation including ~~[[the]]~~ said at least one gas-forming component ~~component(s)~~ by dissolving or suspending the components in a solvent or suspending agent that is substantially free from water;

[[-]] spreading ~~[[this]]~~ said coating compound on a support; and
drying said support[[;]]

~~or comprising the steps of~~

[[-]] ~~preparing a first coating compound which contains a first gas-forming component as well as further components of the film-forming preparation by dissolving or suspending said components in an aqueous solvent or suspending agent;~~

[[-]] ~~preparing a second coating compound which contains a first gas-forming component as well as further components of the film-shaped preparation by dissolving or suspending said components in an aqueous solvent or suspending agent, said first and said second component being reaction partners of a gas-forming reaction;~~

[[-]] ~~spreading the first coating compound on a support and drying, thus forming a first film;~~

[[-]] ~~spreading the second coating compound on a support and drying, thus forming a second film;~~

[[-]] ~~laminating the two films onto each other;~~

~~or comprising the steps of:~~

[[-]] ~~preparing a coating compound which contains the components of the preparation including the gas-forming component(s) by dissolving or suspending the said components in a solvent or a suspending agent, with at~~

least one of the gas-forming components being present in microencapsulated form;

[[-]] spreading this coating compound on a support and drying.

2. (currently amended) ~~Process~~ The process according to claim 1, wherein ~~characterized in that the~~ said at least one gas-forming component ~~component(s) is/are~~ is selected from the group ~~comprising~~ consisting of carbonates, especially sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, especially sodium hydrogen carbonate, and acids, especially citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid, tartaric acid, as well as and acid regulators, especially salts of acetic acid, sodium dihydrogen phosphate or disodium hydrogen phosphate, sodium tartrate, sodium ascorbate.

3. (currently amended) ~~Process~~ The process according to claim 2, ~~characterized in that~~ as wherein said at least one gas-forming components component is a combination of at least one first component ~~[(a)]~~ and at least one second component ~~(b) is used, said~~ component(s), wherein said at least one first component is a carboxylic acid

~~(a) — being selected from the group comprising~~ (a) — being selected from the group consisting of the carboxylic acids, preferably from the group comprising citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said at least one second component components

~~(b) — being~~ is selected from the group ~~comprising~~ consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

4. (currently amended) ~~Process~~ The process according to ~~any one of the preceding~~ claims, characterized in that claim 1, further comprising the step of the production is ~~accomplished under addition of~~ adding ~~[(a)]~~ at least one pharmaceutical active substance to said preparation ~~or a combination of two or more pharmaceutical active~~ substances.

5. (currently amended) ~~Process~~ The process according to ~~any one of the preceding~~ claims, characterized in that claim 1, further comprising the step of the production is ~~accomplished under addition of~~ adding a flavouring agent to said preparation; preferably menthol.

6. (currently amended) A film-shaped ~~Film-shaped~~ preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing at least one

gas-forming component able to ~~or more components which~~ produce a gas upon action of moisture, ~~[[or]]~~ being in the presence of an aqueous medium or ~~in the case of~~ by a temperature change ~~in temperature, produced in accordance with any one of the preceding claims.~~

7. (currently amended) A film-shaped ~~Film-shaped~~ preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing at least one gas-forming component able to ~~or more components which~~ produce a gas upon action of moisture, ~~[[or]]~~ being in the presence of an aqueous medium or ~~in the case of~~ by a temperature change, ~~in temperature, characterized in that~~ wherein at least one of ~~[[the]]~~ said at least one gas-forming ~~components~~ component is ~~present~~ is in a microencapsulated form.

8. (currently amended) A film-shaped ~~Film-shaped~~ preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing at least one gas-forming component able to ~~or more components which~~ produce a gas upon action of moisture, ~~[[or]]~~ being in the presence of an aqueous medium or ~~in the case of~~ by a temperature change ~~in temperature, characterized in that it~~ , wherein said preparation has two film layers ~~which are~~ connected ~~[[with]]~~ to each other, the first film layer containing a first gas-forming component ~~as well as~~ and further components of the film-shaped preparation, and the second film layer containing a second gas-forming component ~~as well as~~ and further components of the film-shaped preparation, ~~[[and]]~~ wherein said first and second gas-forming components ~~being~~ are reaction partners of a gas-forming reaction.

9. (currently amended) ~~Preparation~~ The preparation according to claim 7 ~~[[or 8]]~~, ~~characterized in that the~~ wherein said at least one gas-forming component ~~component(s) is/are~~ is selected from the group ~~comprising~~ consisting of carbonates, ~~especially sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, especially sodium hydrogen carbonate, and acids, especially citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid, tartaric acid, as well as~~ and acid regulators, ~~especially salts of acetic acid, sodium dihydrogen phosphate or disodium hydrogen phosphate, sodium tartrate, sodium ascorbate.~~

10. (currently amended) The preparation ~~Preparation~~ according to claim 9,

~~characterized in that as~~ wherein said gas-forming components comprise a combination of at least one first component ~~[[a)]]~~ and at least one second component ~~(b)-is-used,~~ wherein said at least one first component is a carboxylic acid component(s)

~~(a) — being selected from the group of the carboxylic acids, preferably from the group comprising citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said at least one second component~~
components

~~(b) — being~~ is selected from the group ~~comprising~~ consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

11. (currently amended) Preparation The preparation according to claim 6, wherein ~~any one of claims 6 to 10, characterized in that said preparation is capable of~~ producing produces CO₂ or N₂, ~~preferably under action of water, [[or]] an aqueous medium or moisture.~~

12. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 11, characterized in that it~~ claim 6, wherein said preparation produces an acid environment in the presence of water.

13. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 12, characterized in that~~ claim 6, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 5 min, ~~preferably within 1 s to 1 min, especially preferably within 1 s to 30 s.~~

14. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 12, characterized in that~~ claim 6, wherein said preparation is swellable in aqueous media.

15. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 14, characterized in that~~ claim 6, wherein said preparation further contains ~~[[a)]~~ at least one pharmaceutical active substance ~~or a combination of two or more pharmaceutical active substances.~~

16. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 15, characterized in that~~ claim 6, wherein said preparation further contains a flavouring agent, ~~preferably menthol.~~

17. (currently amended) Preparation The preparation according to ~~any one claims 6 to 16, characterized in that~~ claim 6, wherein said preparation comprises at least two layers.

18. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 17, characterized in that~~ claim 6, wherein said preparation has a thickness between 5 μm and 3 mm, ~~preferably between 10 μm and 1 mm, especially preferably between 20 μm and 500 μm .~~

19. (currently amended) Preparation The preparation according to ~~any one of claims 6 to 18, characterized in that it is formulated as an oral, rectal or vaginal~~ claim 6, wherein said preparation is an administration form selected from the group consisting of an oral administrative form, a rectal administrative form and a vaginal administrative form for administration of pharmaceutical active agents.

20. (new) The process according to claim 2, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

21. (new) The process according to claim 20, wherein said hydrogen carbonate is sodium hydrogen carbonate.

22. (new) The process according to claim 3, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

23. (new) The process according to claim 5, wherein said flavouring agent is menthol.

24. (new) A process for producing a film-shaped preparation for administration of substances to the human or animal body, said preparation being disintegratable in aqueous media and containing at least one water-soluble polymer and at least one gas-forming component which produces a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, comprising the steps of:

preparing a first coating compound which contains a first gas-forming component and further components of the film-forming preparation by dissolving or suspending said components in an aqueous solvent or suspending agent;

preparing a second coating compound which contains said first gas-forming component and further components of the film-shaped preparation by dissolving or suspending said components in an aqueous solvent or suspending

agent, said first and said second components being reaction partners of a gas-forming reaction;

spreading the first coating compound on a support;

drying said support to form a first film;

spreading the second coating compound on a support;

drying said support to form a second film; and

laminating said first film and said second film onto each other.

25. (new) The process according to claim 24, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

26. (new) The process according to claim 25, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

27. (new) The process according to claim 26, wherein said hydrogen carbonate is sodium hydrogen carbonate.

28. (new) The process according to claim 24, wherein said at least one gas-forming component is a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

29. (new) The process according to claim 28, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

30. (new) The process according to claim 24, further comprising the step of the adding at least one pharmaceutical active substance to said preparation.

31. (new) The process according to claim 24, further comprising the step of adding a flavouring agent to said preparation.

32. (new) The process according to claim 31, wherein said flavouring agent is menthol.

33. (new) A process for producing a film-shaped preparation for administration of

substances to the human or animal body, said preparation being disintegratable in aqueous media and containing at least one water-soluble polymer and at least one gas-forming component which produces a gas upon action of moisture, being in the presence of an aqueous medium or by a temperature change, or comprising the steps of:

preparing a coating compound which contains the components of the preparation including said at least one gas-forming component by dissolving or suspending the components in a solvent or a suspending agent, wherein at least one of said at least one gas-forming component is present in a microencapsulated form;

spreading said coating compound on a support; and

drying said support.

34. (new) The process according to claim 33, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.

35. (new) The process according to claim 34, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.

36. (new) The process according to claim 35, wherein said hydrogen carbonate is sodium hydrogen carbonate.

37. (new) The process according to claim 33, wherein said at least one gas-forming component is a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

38. (new) The process according to claim 37, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

39. (new) The process according to claim 33, further comprising the step of the adding at least one pharmaceutical active substance to said preparation.

40. (new) The process according to claim 33, further comprising the step of adding a flavouring agent to said preparation.
41. (new) The process according to claim 40, wherein said flavouring agent is menthol.
42. (new) The preparation according to claim 13, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 1 min.
43. (new) The preparation according to claim 42, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 30 s.
44. (new) The preparation according to claim 16, wherein said flavouring agent is menthol.
45. (new) The preparation according to claim 18, wherein said preparation has a thickness between 10 μm and 1 mm.
46. (new) The preparation according to claim 45, wherein said preparation has a thickness 20 μm and 500 μm .
47. (new) The preparation according to claim 9, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.
48. (new) The preparation according to claim 47, wherein said hydrogen carbonate is sodium hydrogen carbonate.
49. (new) The preparation according to claim 10, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.
50. (new) The preparation according to claim 7, wherein said preparation produces CO_2 or N_2 under action of water, an aqueous medium or moisture.
51. (new) The preparation according to claim 7, wherein said preparation produces an acid environment in the presence of water.
52. (new) The preparation according to claim 7, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 5 min.
53. (new) The preparation according to claim 52, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 1 min.

54. (new) The preparation according to claim 53, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 30 s.
55. (new) The preparation according to claim 7, wherein said preparation is swellable in aqueous media.
56. (new) The preparation according to claim 7, wherein said preparation further contains at least one pharmaceutical active substance.
57. (new) The preparation according to claim 7, wherein said preparation further contains a flavouring agent.
58. (new) The preparation according to claim 57, wherein said flavouring agent is menthol.
59. (new) The preparation according to claim 7, wherein said preparation comprises at least two layers.
60. (new) The preparation according to claim 7, wherein said preparation has a thickness between 5 μm and 3 mm.
61. (new) The preparation according to claim 60, wherein said preparation has a thickness between 10 μm and 1 mm.
62. (new) The preparation according to claim 61, wherein said preparation has a thickness between 20 μm and 500 μm .
63. (new) The preparation according to claim 7, wherein said preparation is an administration form selected from the group consisting of an oral administrative form, a rectal administrative form and a vaginal administrative form for administration of pharmaceutical active agents.
64. (new) The preparation according to claim 8, wherein said at least one gas-forming component is selected from the group consisting of carbonates, acids and acid regulators.
65. (new) The preparation according to claim 64, wherein said carbonates are selected from the group consisting of sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, said acids are selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said acid regulators are selected from the group consisting of salts of acetic acid, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium tartrate and sodium ascorbate.
66. (new) The preparation according to claim 65, wherein said hydrogen carbonate is sodium hydrogen carbonate.

67. (new) The preparation according to claim 64, wherein said gas-forming components comprise a combination of at least one first component and at least one second component, wherein said at least one first component is a carboxylic acid, and said at least one second component is selected from the group consisting of sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

68. (new) The preparation according to claim 67, wherein said carboxylic acid is selected from the group consisting of citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid.

69. (new) The preparation according to claim 8, wherein said preparation produces CO₂ or N₂ under action of water, an aqueous medium or moisture.

70. (new) The preparation according to claim 8, wherein said preparation produces an acid environment in the presence of water.

71. (new) The preparation according to claim 8, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 5 min.

72. (new) The preparation according to claim 71, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 1 min.

73. (new) The preparation according to claim 72, wherein said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 30 s.

74. (new) The preparation according to claim 8, wherein said preparation is swellable in aqueous media.

75. (new) The preparation according to claim 8, wherein said preparation further contains at least one pharmaceutical active substance.

76. (new) The preparation according to claim 8, wherein said preparation further contains a flavouring agent.

77. (new) The preparation according to claim 76, wherein said flavouring agent is menthol.

78. (new) The preparation according to claim 8, wherein said preparation comprises at least two layers.

79. (new) The preparation according to claim 8, wherein said preparation has a thickness between 5 µm and 3 mm.

80. (new) The preparation according to claim 79, wherein said preparation has a thickness between 10 µm and 1 mm.

81. (new) The preparation according to claim 80, wherein said preparation has a

thickness between 20 μm and 500 μm .

82. (new) The preparation according to claim 8, wherein said preparation is an administration form selected from the group consisting of an oral administrative form, a rectal administrative form and a vaginal administrative form for administration of pharmaceutical active agents.